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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/523,767 | 03/11/2000 | Eugene de Juan JR. | 49.603 (1699) | 5862 |

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EXAMINER

BAXTER, JESSICA R

ART UNIT PAPER NUMBER

3731

DATE MAILED: 08/27/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/523,767

Applicant(s)

DE JUAN ET AL.

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 42-66 is/are pending in the application.
- 4a) Of the above claim(s) 42-54, 56-62 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-21, 55 and 63-65 is/are rejected.
- 7) ☐ Claim(s) 14 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,618,594 to Banko.

Banko discloses a method comprising the steps of providing an entry alignment device (FIG. 6-8) and inserting the entry alignment device into the conjunctiva and sclera without a prior incision in the conjunctiva or sclera (Column 6 lines 32-45 and Column 7 lines 14-32).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1- 12, 55 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,487,725 to Peyman in view of Banko '594

Peyman discloses a surgical procedure that does not utilize the use of entry alignment devices. Banko teaches that entry alignment devices are used in surgical procedures to provide stability and a supporting point for the surgeon's hand (Column 7 lines 14-24). It

would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Peyman '725 with the device of Banko in order to provide stability and support for the surgeon performing the procedure on the eye.

Regarding claims 2, 3 and 10, Peyman teaches that the devices used in his procedure are small enough to allow the wound to be self-sealing (Column 4 line 65-67).

Regarding claims 4, 5, 8 and 9, Peyman discloses that a surgical instrument used in the procedure is less than 25 gauge and may be an infusion cannula or an vitreous cutter or aspirator (Column 2 lines 7-19 and Column 5 lines 15-17).

Regarding claim 6, Banko discloses that the entry alignment device is in the form of a metal cannula .

Regarding claims 7 and 55, Peyman discloses that a plurality of entry alignment devices may be inserted into the eye (FIG. 11).

Regarding claims 11 and 12, Peyman discloses that the device is inserted at an angle with respect to a normal to the eye (FIG. 5). The normal to the eye can be any line that is perpendicular to the eye.

Regarding claim 63, Peyman discloses that the infusion cannula may be inserted directly through the sclera and conjunctiva or through the entry alignment device (Column 4 lines 36-62).

5. Claims 13, 15-21, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman '725 in view of Banko '594, further in view of U.S. Patent No. 5,919,158 to Saperstein et al.

Peyman discloses the claimed invention except for the insertion of a light source. Saperstein teaches the use of a light source to illuminate an area the surgeon is working on (see Column 5 lines 13-15). Therefore, it would have been obvious to one having ordinary

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skill in the art at the time the invention was made to insert a light source in order to illuminate the area in which the surgeon is working.

Regarding claim 13, Peyman discloses inserting a high-speed vitreous cutting/aspirating instrument and removing vitreous gel using the high-speed vitreous cutting instrument and implementing a corrective procedure for the retina (see Column 4 line 63 – Column 5 line 18).

Regarding claims 15, 16 and 19, Banko discloses the claimed invention except for the size necessary to ensure a self-sealing entry aperture. Peyman teaches that the devices used in his procedure are small enough to allow the wound to be self-sealing (Column 4 line 65-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to size the entry alignment device of Banko small enough to be self-sealing in order to avoid the use of sutures.

Regarding claim 17, Banko discloses that the entry alignment device is in the form of a metal cannula

Regarding claim 18, Peyman discloses that a surgical instrument used in the procedure is less than 25 gauge and may be an infusion cannula (Column 4 lines 38-46).

Regarding claims 20 and 21, Peyman discloses that the step of inserting includes inserting the instruments, hence the entry alignment device, at an angle less than 45 degrees with respect to a normal to the eye.

Regarding claims 64 and 65, Peyman discloses that the infusion cannula may be inserted directly through the sclera and conjunctiva or through the entry alignment device (Column 4 lines 27-46).

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Allowable Subject Matter

6. Claims 14 and 22 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

7. Applicant's arguments with respect to claims 1-22, 55 and 63-65 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization

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where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
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JRB
jrb

August 21, 2003


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700